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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,879

05/10/2006

Earl M. Zergiebel

2909 US

2518

50855

7590

03/17/2009

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EXAMINER

PHILOGENE, PEDRO

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

03/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,879	<b>Applicant(s)</b> ZERGIEBEL, EARL M.	
	<b>Examiner</b> Pedro Philogene	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-22 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-22 and 25-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/08; 9/30/08; 1/5/09</u> .                                | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al. (2003/0158555) in view of Reed (5,868,749).

Sanders et al disclose an absorbable screw fastener/surgical screw system a body portion/shank having a proximal end and a distal end, the body portion/ shank being threaded, as set forth in para [29], and the head portion having an outer diameter substantially equal to the first distance of the helical, as set forth in para[97]. Sanders et al discloses a device where the fastener is formed of PGA/PLA and PGA, as set forth in para[37,39 and 41]. Sanders et al teach a fastener wherein the distal end is blunt, as best seen in FIG.1c. Sanders et al teach of a fastener device wherein the land of the thread is substantially perpendicular to the longitudinal axis and wherein a distance of the thread is substantially enlarged, as best seen in FIG.1B. Sanders et al teach a fastener which has a minimum head portion diameter of 3.5 mm and a maximum head portion diameter of 4.5 mm; as set forth in para[107]. Sanders et al teach of a fastener with a body portion having a circular cross-section, as best seen in FIG.1a. As to the head portion having height of about 1.5mm and the a length of the body portion having a length of about 5 mm, it would have been obvious to one having ordinary skill in the art at the time the invention was made to reach the optimum range, since it has been

Art Unit: 3733

held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

It is noted that Sanders et al did not teach of a head portion having a driver receiving structure formed in an outer radial side surface of the outer diameter, the driver receiving structure being configured for receiving both a linear and a rotational force; as claimed by applicant. However, in similar art, Reed (FIGS.24,25) provides the evidence of the use of a screw having a driver receiving structure formed in an outer radial side surface of the outer diameter, the driver receiving structure being configured for receiving both a linear and a rotational force to provide rotational movement to the device and to facilitate insertion of the device.

Therefore, given the teaching of Reed, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sanders et al, as taught by Reed to provide rotational movement to the device and to facilitate insertion of the device.

The method steps, as set forth, would have been obviously carried out in the operation of the device as set forth above; since Reed discloses the use of a pin or guide wire.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al. (2003/0158555) in view of Reed (5,868,749) in view of Fitts et al. (6,096,060).

It is noted that the above combination of references discloses all the limitations, except for the body portion of the fastener including a center shaft which is tapered. Fitts et al disclose a shaft that can be tapered, as set forth in column 4, lines 55-65.

Art Unit: 3733

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the tapered shaft of Fitts et al., in Sanders et al to offer an equivalent means of fitting a tapered screw, tap or guide into the shaft.

Claims 15-17, 19-22, 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al. (2003/0158555) in view of Reed (5,868,749) in view of Becker (2,248,054).

With respect to claims 15-17, 19-22, 25-32, it is noted that Sanders et al and Reed discloses all the limitations, such as an absorbable screw and a method of transmitting both the axial and rotational force to the absorbable screw. It is however noted that the above combination of references did not teach of an instrument for inserting the absorbable screw fastener comprising a distal portion having an elongated outer tube and a proximal portion having a trigger mechanism and a driver/torque subassembly disposed within the outer tube and being movable relative to the outer tube including at least a pair of resilient force transmitting arms extending distally therefrom configured to provide at least a partial passage for a fastener therethrough; as claimed by applicant. However, in similar art, Becker provides the evidences of the use of such an instrument whereby the screw may be driven in bone structure without danger of slipping or misdirecting the screw.

Therefore, given the teaching of Becker, it would have been obvious to one having ordinary skill in the art, at the time the invention was made to modify the device

Art Unit: 3733

of Sanders et al. Reed, by using the insertion instrument of Becker Whereby the screw may be driven in bone structure without danger of slipping or misdirecting the screw.

As to a trigger mechanism that comprises a ratchet mechanism; at the time of the invention, it would have been obvious to a person of ordinary skill in the art to use a ratchet mechanism in Becker's device. Official Notice is taken that a ratchet mechanism of inserting the absorbable screw fastener.

It is also noted that the above combination of references did not teach of a fastener having a distal body portion angled at 5 to 15 degrees, a head portion angled at 5 to 15 degrees, and a distal end of the body portion angled at 5 to 15 degrees; as claimed by applicant. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sanders by constructing the angle measurements with respect to the longitudinal axis to be between 5 and 15 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. I re Aller 105 USPQ 233.

### ***Response to Amendment***

Applicant's arguments with respect to claims 1-32 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 3733

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pedro Philogene/  
Primary Examiner, Art Unit 3733  
March 14, 2009